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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,113	02/16/2001	Shou-Wei Ding	2577-114	2556
6449	7590	12/17/2003	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,113	DING, SHOU-WEI	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26 and 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 14 July 2003, Applicant has cancelled claims 1-23 and 27-29 as being drawn to nonelected subject matter. Applicant has amended claims 24-25, 30-33, and 35-36. Claims 24-26 and 30-37 are pending, and are examined in the instant action.
2. This action is made FINAL necessitated by Applicant's amendment.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-second

5. Claims 24-26 and 30-37 are rejected under 35 U.S.C. 112-2nd.

In claim 24,

- What is an "Avr protein"?

In claims 25 and 31, "derived" remains rejected for reasons of record, namely, "derived" is unclear because this can mean the ancestry or the source. If it means the source, it is not clear what is maintained and what is left behind, of the source material.

Applicant traverses, stating primarily that "derived " is an often used term in molecular biology , with a meaning well-known to persons of ordinary skill in the

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art, and used consistently in the specification in a manner consistent with this customary meaning.

Applicant's traversal has been considered and is unpersuasive. Applicant has not clarified this terminology. The ambiguity of this word remains.

Claim Rejections - 35 USC § 112, first paragraph

Written description

6. Claims 24-26 and 30-37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record, which are reiterated below:

Claim 24 is drawn to a transgenic plant stably transformed with a two-domain Avr gene having an inactive cell death domain, operatively linked to a promoter that is capable of effecting expression of said gene in said plant when said plant is infected with a pathogenic organism.

Claim 25 is drawn to an Avr gene derived from the cucumovirus 2b gene.

Claim 26 is drawn to an Avr gene which is a chimera of the resistance domain of Tav2b and the cell death domain of the Cmv2b gene.

Claim 30 is drawn to an expression vector comprising an Avr gene having an inactive cell death domain operably linked to a plant-active promoter.

Applicants recite various functional components, but give no information on the structure(s) required for the function(s). Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Applicant traverses, stating primarily (Response. p. 9) that the instant case is different from the cited University of California v. Eli Lilly case, where the Applicant simply claimed the cDNA "encoding insulin". That in the present case the term refers to a well-published and specific class of known gene sequences. Applicant asserts (Response, p.8) that the claims recite DNA sequence encoding Avr proteins, and particular domains thereof. That this is not a functional description of DNA, but a recitation of a class of known sequences.

Applicant's traversal has been considered and is unpersuasive. The present claims lack any description of structures or structural features that define the genus.

Claim Rejections - 35 USC § 112-Enablement

7. Claims 24-26 and 30-37 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record, which are reiterated below. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

The specification, while being enabling for

- A transgenic plant stably transformed with a two-domain Avr gene wherein the Avr gene is a chimera of the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, where the cell death domain is operatively linked a promoter that is capable of effecting expression of the gene in the plant when the plant is infected with a pathogenic virus, where the transgenic plant is tobacco or tomato.

does not reasonably provide enablement for

- Any two-domain Avr gene, or any plant or any pathogenic organism, or the broad scope of the claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enablement issues are: the two-domain Avr gene under control of a promoter activated by infection with a plant pathogen, any pathogenic organism, and transgenic plants other than tomato and tobacco.

Applicant teaches a two-domain Avr gene comprising a both the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, under the control of the U1 sgRNA promoter of TMV (Example 8, p28). Applicant further teaches that PR proteins are induced in wild-type tobacco following inoculation with a TMV-2vb virus.

- There is no teaching of the two-domain Avr gene under the control of a plant pathogen activated promoter. (End of citation of previous Office Action)

While one skilled in the art can readily make constructs of viral coding sequences and promoters, making a two-domain Avr gene under the control of a plant pathogen activated promoter construct such that the genes are activated upon infection of a transgenic plant comprising the 2-domain Avr gene, by a pathogenic organism, without further guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, is excessive experimentation and an undue burden.

While one working example may enable a broader scope, Applicant has not provided a single working example of a two-domain Avr gene under the control of a plant pathogen activated promoter. Applicant does not show the physical configuration of the claimed constructs—what the linear relationship of the various domains is, what is first and what second, whether the whole “domains” or only parts thereof are required for function, what proximity is required for the “domains” to provide the desired function, or what promoter functions to give the claimed result. Applicant teaches

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a viral subgenomic promoter but claims any promoter capable of causing expression in the plant when the plant is infected any pathogenic organism. Applicant has given no evidence that any such promoter would be able to express the DNA of interest in the plant material, transiently or otherwise. While working examples are not required, Applicant must provide sufficient guidance to address these issues. Without such guidance, the experimentation required would not be routine, but would be undue.

Remarks

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

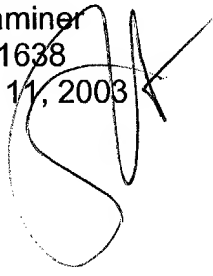
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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. *Note that Examiner's phone number will change to 571-272-0796 as of 6 January 2004.*

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
December 11, 2003




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600